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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/534,208  | 11/02/2005  | Lidia Elfstrand      | 05822.0323USWO               | 9970                   |
| 23552 7590 04/28/2009<br>MERCHANT & GOULD PC<br>P.O. BOX 2903<br>MINNEAPOLIS, MN 55402-0903 |             |                      | EXAMINER<br>BASQUILL, SEAN M |                        |
|   |             |                      | ART UNIT<br>1612             | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>04/28/2009      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/534,208 | <b>Applicant(s)</b><br>ELFSTRAND ET AL. |  |
|                              | <b>Examiner</b><br>Sean Basquill     | <b>Art Unit</b><br>1612                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>29 Sep 2008; 11 Mar 2009</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Previous Rejections***

1. Applicants' arguments, filed 18 February 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-13 and 15-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,202,546 ("Scammell"), in view of U.S. Patent 3,689,290 ("Blackstock") as put forth in the previous action.

Applicants arguments have been fully considered but are deemed unpersuasive. While Scammell provides many examples incorporating the colostrum concentrate into liquid dairy products, Scammell additionally indicates the colostrum obtainable through their process may be incorporated into solid dairy products such as cheese formulations. Scammell, more properly speaking, is therefore directed to methods of providing colostrum-based immunotherapy via fortified dairy products. Because prior art is art for all that it expressly discloses and reasonably suggests to the ordinarily skilled artisan, MPEP § 2123, Scammell therefore suggests the desirability of incorporating colostrum into solids such as cheese formulations. Because

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Blackstock is also directed to cheese formulations, the ordinarily skilled artisan would clearly be motivated to incorporate the colostrum therapy disclosed by Scammell. Additionally, the examiner directed the applicants to the teaching of Blackstock concerning the particulate size, as pointed out in the previous action. Blackstock clearly invites the particle size optimization relied upon by the examiner via the express teaching that such particle size may be adjusted to a desired size and configuration, with the general condition of particles of between 12-100 mesh disclosed. Given this teaching, and absent any secondary indicia of nonobviousness, the rejection is proper.

Applicants arguments that Scammell "teaches away from" the incorporation of colostrum into the cheese product of Blackstock are misplaced. For a reference to properly "teach away" from the combination of references, the art must render the prior art unsatisfactory for its intended purpose, change the principle of operation of a reference, or "criticize, discredit, or otherwise discourage the solution claimed," MPEP § 2145(X)(D). As described above, the disclosure of Scammell is more properly characterized as teaching the incorporation of immunotherapeutic colostrum into dairy products, such as the cheese product described by Blackstock. The disclosure of neither Scammell, nor Blackstock, nor the optimization of the particulate size advanced by the examiner, render the prior art unsatisfactory for its intended purpose, change the principle of operation of a reference, or criticize, discredit, or otherwise discourage the solution claimed.

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3. Claims 1-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scammell and Blackstock, as applied to Claims 1-13 and 15-17 above, and further in view of U.S. Patent 5,846,569 ("Anderson") as put forth in the previous action.

Applicants arguments have been fully considered but are deemed unpersuasive.

Applicants arguments concerning the combination of Scammell and Blackstock, as well as the optimization of the prior art particulate size, have been addressed by the examiner above. In addition, applicants comments concerning the beneficial effects of bovine colostrum for patients with gastrointestinal symptoms are considered irrelevant in view of the claims presented, which are directed to compositions, and not methods of treating gastrointestinal symptoms using bovine colostrum.

### ***Conclusion***

No Claims stand allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill  
Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612

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